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09/770,703	01/26/2001	Brent Delzer	S-50063P1	6804

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EXAMINER

IBRAHIM, MEDINA AHMED

ART UNIT

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Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)
	09/770,703	DELZER, BRENT
	Examiner Medina Ibrahim	Art Unit 1638

-- The MAILING DATE of this communication appears on the cover sheet with the corresponding address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM  
THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1) Responsive to communication(s) filed on 25 June 2002.

2a) This action is **FINAL**.                            2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4) Claim(s) 1-49 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5) Claim(s) 1-5,16-22 and 25-28 is/are allowed.

6) Claim(s) 6-15,23,24 and 29-49 is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All    b) Some \* c) None of:

1. Certified copies of the priority documents have been received.

2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.

3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____	6) <input type="checkbox"/> Other: _____

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## DETAILED ACTION

Applicants' response of 06/25/02 has been entered. New claims 43-49 have been added. Therefore, claims 1-49 are pending and are under examination. All previous rejections and objections not stated below have been withdrawn.

This Office action contains NEW GROUNDS OF REJECTION not necessitated by Applicants' amendments. Therefore, this action is non-final. The delay in applying these new grounds of rejection is regretted.

### ***Claim Rejections - 35 USC § 112, 2nd paragraph***

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 42 remains rejected and claims 6-8, 15, 33-34, 38-39, and 48 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 42 remain rejected as the metes and bounds of what is retained in "NP2174-derived" are unclear. Also, the claim remains indefinite in the recitation of the relative terms that lack comparative basis, as stated in the last Office action. Applicants' arguments in page 9 of the response have been considered but are not found persuasive because no quantitative definition or description of "acceptable to

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good," "good," "above average," "acceptable," "reliable," and "adapted" have been disclosed. These terms are not described in Table 1 of the specification, and the reference to plant A632 is not recited in the rejected claim. Furthermore, neither the individual traits nor their degree of expression is unique to NP2174.

Claim 6, drawn to a male sterile maize plant or parts thereof, is indefinite as it is unclear how a male sterile maize plant would result from the non-male sterile maize plant of claim 2.

In claims 7-8, 38, 40-41, and 43-46 the metes and bounds of "a single gene transferred traits," "single gene trait," or "transgene" are unclear as the phrase or the term does not carry with it any limitations as to the structural or physiological properties of the gene. Dependent claims 15 and 33-34 are included in the rejection.

In claims 8 and 45, is the "one or more transgene" in addition to the "one or more single gene transferred traits"?

Claim 45 does not further limit claim 8.

In claim 48, "A maize plant breeding program" should be replaced with ---The method---, and ---the --- should be inserted after "wherein," for clarification. Applicants should note that claim 47 is not drawn to a maize plant breeding program.

#### ***Claim Rejections - 35 USC § 112, Enablement***

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:  
The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled

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in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 6-15, 23-24, and 29- 49 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Claims are drawn to a maize plant or parts thereof that have been transformed or introgressed so that its genetic material contains one or more single gene transferred traits which include genes that confer herbicide, insect, virus and disease resistance or male sterility, and a method of introgressing a single gene trait into the inbred maize line NP2174 by using markers associated with a single gene trait so that resultant inbred maize NP2174 further comprises said a single gene transferred traits. The claims also encompass F1 maize plants/seeds as well as subsequent generation maize introgressed or transformed plants, or the plants or parts thereof produced by crossing the maize inbred line NP2174 with unidentified maize inbred lines, and methods of using the introgressed or transformed plants, or the F1 and subsequent generations in additional crosses.

Applicant has not disclosed or provided guidance for a transformed or non-transformed maize inbred line NP2174 or parts thereof further comprising introgressed one or more single gene traits, or a trait such as herbicide tolerance, disease or insect resistance transferred by introgression such as backcrossing. No guidance has been

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provided for the obtention of F1 generation or subsequent generation maize plants, in addition to the single gene traits introgressed to the inbred or a method for producing said plants. While the transformation of a plant with a transgene that confers desired traits is well within the level of one skilled in the art, the state of the art teaches that it is unpredictable whether a gene or genes for conferring a phenotype in one plant genotypic background may be introgressed into the genetic background of another plant to confer the phenotype in said different plant. For example, Hunsperger et al (US Patent No. 5, 523, 520 ) disclosed a specific gene trait in the genetic background of one plant which has been introgressed into the genetic background of another plant of the same species, that didn't result in the expected transfer gene trait ( column 3, lines 26-46). Kraft et al teach that linkage disequilibrium effects and linkage drag prevent the making of plants comprising a single transferred trait, and that such effects are unpredictably genotype specific and loci dependent in nature. Kraft et al teach that linkage disequilibrium is created in breeding materials when several lines become fixed for a given set of alleles at a number of different loci, and that very little is known about the plant breeding material, and therefore, is an unpredictable effect in plant breeding (page 323, column 1, line 7 to line 15). See also, Eshed et al who teach that in plants, epistatic genetic interactions from the various genetic components comprising contributions from different genomes may affect quantitative traits in a genetically complex and less than additive fashion (page 1815, column 1, line 1 to page 1816,

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column 1, line 1). Neither the instant specification nor the prior art provides evidence that such linkage disequilibrium, linkage drag, or epistatic effects are not common in maize breeding materials, such that one or more single gene traits can be transferred (introgressed) from one genetic background to another.

Therefore, given the lack of guidance in Applicants specification regarding introgression of single trait genes in maize inbred line NP2174, the lack of guidance regarding the isolation of a multitude of non-exemplified transgenes or their evaluation in particular maize genetic backgrounds, the state of the art, the unpredictability inherent in introgressing single gene traits, and lack of working examples, one skilled in the art would not be able to make a transformed maize inbred line NP2174 or parts thereof further comprising one or more single gene transferred traits, or NP2174-derived plants including F1 and subsequent generation plants, without undue experimentation.

***Written Description***

Claim 42 remains rejected and claims 6-15, 23-24 and 29-49 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 42 lacks written description for the reasons set forth in pages

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4 and 5 of the last Office action. Applicants' arguments of 06/25/02 have been fully considered but are not found persuasive.

Applicants assert that NP2174-derived plants have been adequately described and that Examiner allegedly appears to be mixing the enablement requirement with the written description requirement (p. 9 of the response). These assertions are incorrect because in pages 12-15 of the specification Applicant only describes the inbred maize line NP2174, deposited as Accession no. PTA- 2970, which has specific genotypic and phenotypic characteristics that distinguish the line from other maize lines. Nowhere in the specification was an NP-2174- derived plant, including an F1 plant or subsequent generation plant disclosed or completely characterized by genotype or phenotype. Further, Applicant has not described any phenotypic trait that distinguishes NP2174-derived maize plants or introgressed NP2174 maize plants comprising linked quantitative or single genes of unknown characteristics, including F1 and subsequent generation plants, from other maize plants. In addition, Applicant has not described a multitude of non-exemplified transgenes, or their phenotypic effects in particular maize genetic backgrounds. Therefore, absent such description one skilled in the art would not know that Applicants were in possession of the plant of claim 42. Applicants should note that if a plant is not adequately described, one skilled in the art would not be able to make or used the plant. Therefore, the alleged confusion of the written description requirement with the enablement requirement does not rebut the Examiner's position.

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In addition, since Applicant has not described even F1 generation plants of claims 23-24, 29-30, 35-39, and 47-49, subsequent generation plants or methods of their use have not been similarly described. Applicants should also note that because various breeding techniques and a multitude of uncharacterized breeding partners and breeding generations (claims 47-48) have been employed to produce said plants, substantial variation in structure and phenotype are expected among the plants.

Regarding the arguments that the novelty of claim 42 resides in the maize inbred line NP2174 and two or more of its derived traits, it is noted that the rejected claim requires NP2174 as an ancestor and the two or more traits are disclosed with a relative term lacking comparative basis. Since NP2174 may have been used only in the first generation cross and the identity of other parents involved in first and subsequent crosses are not disclosed, the claimed plant retains very little, if any, NP2174 - derived traits. In addition, the novelty of inbred line NP2174 resides in its unique combination of genetic and morphological traits as a whole rather than the expression of two or few traits as claimed in claim 42. Therefore, the requirements that NP2174 be an ancestor of the plant, and that the plant expresses a combination of at least two NP2174 traits, do not provide an adequate written description for the claimed NP2174-derived plant, absent further description. Therefore, one skilled in the art would not recognize from the disclosure that Applicants are in possession of the invention as broadly claimed.

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Regarding the *Eli Lilly* case, the examiner maintains the two situations are analogous, where the genus/species requirements are not met. In both situations, the description of one species of a genus ( rat insulin encoding cDNA, in Eli Lilly, and a maize inbred line NP2174, in the instant application) has been sought to describe the genus, vertebrate/mammalian insulin cDNA and NP2174-derived maize plants. The court in Eli Lilly has determined that the description of a genus may be achieved by disclosing a representative sample of species falling within the scope of the genus or a structural features common to members of the genus, which features constitute a substantial portion of the genus. This also true in the *Synopsis of Application of Written Description Guidelines* ( page 9, section entitled, *Written Description, Original Claims*).

Claims 6-15, 31-36, 40-46 are included in the rejection because the claims do not characterize the sequence or identity of the transgenes or introgressed genes, or recite phenotypic effects of expression of the “one or more transgenes”, “single gene transferred traits”, or the “single gene traits”, and therefore, the maize plants or plant parts transformed with or comprising said one or more transgenes, or a method for using or producing said plants and plant parts are not similarly described. Therefore, one skilled would not recognize that Applicants are in possession of the claimed invention.

Accordingly, the claimed invention lacks adequate written description as required under the current written description guidelines (See Written Description

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Requirement published in Federal Registry/Vol. 66, No. 4/Friday, January 5, 2001/Notices; P. 1099-1111).

### **Claim Rejections - 35 USC § 102/103**

Claim 42 remains rejected and new claim 49 is rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Mies et al (US Patent 5, 792, 906(A)), as stated in the last Office action. Applicants' response filed on 06/25/02 has been considered but not found persuasive.

Applicants' arguments against anticipation or obviousness are not persuasive because the rejected claim is not drawn to a maize plant having all of the morphological and physiological characteristics of maize inbred line NP2174. The claim is drawn to a NP2174-derived maize plant or parts thereof having at least one ancestor of maize inbred line NP2174 and a combination of two or more traits selected from a Markush list of traits. Given the lack of identifying characteristics that distinguishes a NP2174-derived corn plant from the prior art maize plant, and the claim language "acceptable to good", "average....." "good ....", above average", " improved stalk", "reliable ....", and "adapted" which are relative terms lacking comparative basis, it is maintained that all claim limitations are anticipated by or, in the alternative, are obvious over the prior art, as stated in the last Office action. Furthermore, the individual traits recited in claim 42 are not unique to NP2174 in either their presence or their degree of expression.

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Applicants should note that the limitations described in Table 1 of the specification are not recited in the rejected claim.

***Remarks***

Claims 1-5, 16-22, and 25-28 are allowed.

Papers relating to this application may be submitted to Technology Sector 1 by facsimile transmission. Papers should be faxed to Crystal Mall 1, Art Unit 1638, using fax number (703) 308-4242. All Technology Sector 1 fax machines are available to receive transmissions 24 hrs/day, 7 days/wk. Please note that the faxing of such papers must conform with the Notice published in the Official Gazette, 1096 OG 30, (November 15, 1989).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Medina A. Ibrahim whose telephone number is (703) 306-5822. The Examiner can normally be reached Monday -Tuesday from 8:00 AM to 5:00 PM and Wednesday-Thursday from 9:00AM to 3:00PM

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Amy Nelson, can be reached at (703) 306-3218.

Any inquiry of a general nature or relating to the status of this application should be directed to the receptionist whose telephone number is (703) 308-0196.

September 5, 2002  
mai



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